BAF/3738

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Weadock et al.	Examiner:	P. Prebilic
Serial No.:	09/391,762	Group Art Unit:	3738
Filed:	September 8, 1999	Docket:	498-36 RES
For:	TUBULAR EXPANDED POLYTETRAFLUOROETHYLENE IMPLANTABLE PROSTHESES	Dated:	November 26, 2001

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on

Date: November 26, 2001

Signature: Linda J. Scheurle
Linda J. Scheurle

Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF PURSUANT TO 37 C.F.R. §1.192

Sir:

This is an appeal to the Board of Patent Appeals and Interferences from a decision mailed July 26, 2001 wherein the Examiner finally rejected claims 1-18. No claims of this application have been allowed. Appellants have timely filed a Notice of Appeal by certification on ~~July~~ Sept. 26, 2001. This Brief is being filed in support of that Notice of Appeal. As required by 37 C.F.R. §1.192, this Brief is being filed in triplicate. The fee for filing this Brief of $320.00 is provided by enclosed check. Please charge any additional fees or credit any overpayments to Deposit Account No. 08-2461.

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I. REAL PARTY IN INTEREST

The real party of interest in the present appeal is Meadox Medicals, Inc., assignee of the entire right, title and interest in and to the above-identified application.

II. RELATED APPEALS AND INTERFERENCES

No related appeal or interferences are presently pending which are known to Appellants, Appellants' legal representative, or assignee which will directly affect, be directly affected by, or have a bearing on the Board's decision on this Appeal. For completeness, it is noted that during prosecution of the parent patent from which the present case is a reissue, an appeal to the Board of Patent Appeals and Interferences was taken.

III. STATUS OF THE CLAIMS

Claims 1-18 are pending and stand finally rejected in this application. The rejection of claims 1-18 is being appealed.

Claims 13-18 are rejected under 35 U.S.C. §251 as being an improper recapture of broadened claim subject matter surrendered in the application for the patent on which the present reissue is based.

Claims 13 stands rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,290,271 to Jernberg (hereinafter "Jernberg"). In the alternative, claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Jernberg.

Claims 1-8 and 11-18 are rejected under 35 U.S.C. §102(b) as being anticipated by an article entitled, "Plasma Modification and Collagen Binding to PTFE Grafts" by Tran et al. (hereinafter "Tran"). In the alternative, claims 1-8 and 11-18 are rejected under 35 U.S.C. §103(a) as obvious over Tran in view of U.S. Patent No. 4,193,138 to Okita (hereinafter "Okita").

Claims 1-10, 13-16 and 18 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,197,977 to Hoffman, Jr. et al. (hereinafter "Hoffman") in view of Okita.

Claims 1-8, 11, 13-16 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,037,377 to Alonso in view of Okita.

IV. STATUS OF AMENDMENTS

The Examiner finally rejected the claims of the above-identified application in an Office Action mailed July 26, 2001. No further response has been presented since the final rejection.

V. SUMMARY OF THE INVENTION

The invention defined by the claims on appeal relates to an implantable prosthesis including a body of expanded polytetrafluoroethylene (hereinafter "ePTFE") having an expanded structure defined by spaced-apart nodes interconnected by fibrils. The node and fibril structure defines voids or pores within the body of the device (specification at page 2, lines 45-59 and Figure 1). A biodegradable composition of natural origin is contained within the pores of the ePTFE structure (specification at page 2, lines 45-48). The biodegradable composition forms a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment (specification at page 3, lines 55-67).

In a preferred embodiment the biodegradable material of natural origin is insoluble at a pH of about 7.4 and is cross-linked to form a solid precipitate (specification at page 6, lines 11-15).

VI. ISSUES ON APPEAL

The issues on appeal are as follows:

1. Whether claims 1-8 and 11-18 are anticipated under 35 U.S.C. §102(b) by Tran.

2. Whether claim 13 is anticipated under 35 U.S.C. §102(e) by Jernberg

3. Whether claims 1-8 and 11-18 are unpatentable under 35 U.S.C. §103(a) as obvious over Tran in view of Okita.

4. Whether claims 1-10, 13-16 and 18 are unpatentable under 35 U.S.C. §103(a) as obvious over Hoffman in view of Okita.

5. Whether claims 1-8, 11, 13-16 and 18 are unpatentable under 35 U.S.C. §103(a) as obvious over Alonso in view of Okita.

6. Whether claim 13 is unpatentable under 35 U.S.C. §103(a) as obvious over Jernberg.

7. Whether claims 13-18 constitute an improper recapture under 35 U.S.C. §251.

VII. GROUPING OF CLAIMS

Claims 1-12 should be considered as one grouping. Claims 13-18 should be considered as a second, separate grouping.

For the purposes of the present Appeal, it is respectfully submitted that independent claims 1 and 13 meet the statutory criteria for patentability. The patentability of the dependent claims will be predicated thereon.

VIII. ARGUMENTS

A. REJECTIONS UNDER 35 U.S.C. §102

1. The rejection of claims 1 and 13 under 35 U.S.C. §102(b) as being anticipated by Tran

Tran discloses a PTFE graft where collagen is applied to the external surface of the graft as a coating. The Tran coating is applied by soaking the PTFE graft with collagen material. The only graft disclosed in Tran is a PTFE graft. Tran does not disclose the use of ePTFE grafts. Failing to disclose ePTFE as a graft material, the Tran reference also therefore fails to disclose a porous substrate.

Claims 1 and 13 specifically recite an implantable device comprising an ePTFE substrate having a structure of spaced-apart nodes and fibrils with pores present between the nodes and fibrils. Failing to clearly disclose an ePTFE substrate having pores present within the node and fibril structure, Tran cannot as a matter of law be anticipatory of claims 1 and 13.

The Examiner notes that Tran discusses the use of a Gortex vascular graft. The Examiner asserts that:

> Gortex is a type of expanded PTFE because this trade name refers precisely to the expanded form of PTFE. If Applicant would like verification of this fact, the Examiner could provide a copy of U.S. Patent No. 5,207,709 which

describes Gortex as expanded PTFE. (Office Action mailed July 26, 2001, at page 10)

It is well settled that in order for a reference to be anticipatory, each and every element of the claimed invention must be disclosed in a single prior art reference. *In re Spada*, 15 USPQ 2d 1655 (Fed. Cir. 1990). The Tran reference fails to disclose that the vascular substrate is ePTFE having the claimed node and fibril structure which results in the claimed pores. The Examiner therefore supplements the Tran reference by relying on trademark usage and reference to a secondary citation. The Examiner makes the assumption that the Tran article recognizes the specific characteristics of a trademarked product without any further description within the reference. Clearly, the use of a trademark to describe a product in a reference cannot impart to that product, characteristics not fully disclosed in the reference. What the particular characteristics of a trademark product were at the time of the Tran reference is pure speculation, inasmuch as neither Tran nor the Appellant controls what goods are used in association with the trademark.

The Examiner offers to further supplement the rejection by citation to U.S. Patent No. 5,207,709 which the Examiner contends describes Gortex as expanded PTFE. In order for the Examiner to reject the present claims based upon a product description contained in a secondary reference, the Examiner's rejection should be under 35 U.S.C. §103, combining the primary and secondary references. No such rejection has been offered during prosecution. As such, the Examiner's rejection under 35 U.S.C. §102 in view of Tran is believed to be in error.

Notwithstanding the above, and assuming, *arguendo*, that Tran acknowledges use of a porous ePTFE graft, there is no disclosure whatsoever in Tran, that pores of the graft contain a biodegradable composition therewithin. In contrast, the graft of Tran is surface treated to enable collagen to be covalently bonded thereto. Failing to clearly disclose each and every claimed element, Tran cannot be anticipatory of claims 1 and 13 of the present invention.

Accordingly, the reversal of the Examiner's rejection of claims 1 and 13 as being anticipated by Tran is warranted.

2. The rejection of claim 13 under 35 U.S.C. §102(e) as being anticipated by Jernberg

Jernberg discloses an implantable tubular structure formed of ePTFE. Jernberg coats this tubular structure with timed-release microparticles containing a chemotherapeutic agent. The microparticles are designed to release the chemotherapeutic agent into the bloodstream over time. There is no disclosure in Jernberg of the chemotherapeutic microparticles filling the pores of the ePTFE structure so as to establish a site for cellular attachment. While the Jernberg microparticles may enter the pores during the coating process, they do not substantially fill the pores or establish a cellular attachment site. The microparticles of Jernberg are specifically designed for degradation shortly after implantation. Therefore, the microparticles of Jernberg could not serve as a cellular attachment site.

Claim 13 specifically recites a biodegradable composition contained within the pores of the prosthesis which forms an insoluble substrate site for cellular attachment. As Jernberg

fails to disclose such an insoluble substrate site for cellular attachment, Jernberg as a matter of law cannot be anticipatory of claim 13.

The Examiner's rejection of claim 13 is therefore believed to be in error and reversal is warranted.

B. REJECTIONS UNDER 35 U.S.C. §103

1. The rejection of claims 1-8 and 11-18 as being obvious over Tran in view of Okita

As noted above, Tran is deficient in that Tran fails to disclose within the reference, the use of expanded polytetrafluoroethylene which defines a porous structure and, as importantly, fails to disclose that biodegradable composition is disposed within the pores to serve as a cellular attachment site. The Examiner recognizes that "one may not consider Tran et al. (article) as anticipating patent because it does not explicitly disclose the node and fibril structure set forth in the present claims" (Office Action mailed July 26, 2001 at page 4). The Examiner therefore alleges that Okita teaches such a node and fibril structure. The Examiner concludes that it would have been obvious to use the graft of Okita as a substrate in the Tran reference.

It is initially noted that Okita includes no disclosure of a biodegradable composition, which as recited in claim 13, at selected conditions of temperature pH forms an insoluble substrate site for cellular attachment. Okita specifically discloses modifying the surface of an

ePTFE structure so that the surface becomes hydrophobic and also provides a polymer in the pores of the ePTFE structure which forms a film of water molecules to prevent absorption of plasma protein which can cause fibrin deposition (Okita at column 3, lines 18-27). The Okita graft is specifically designed to prevent absorption of plasma protein into the graft structure. In that regard, Okita specifically teaches away from cellular attachment. Thus, even if properly combinable, Tran and Okita still fail to disclose, teach or suggest an implantable prosthesis having a biodegradable composition within the pores which forms an insoluble substrate site for cellular attachment. At the very point at which Tran is deficient, i.e., failing to disclose or suggest pores which are filled with a biodegradable composition to establish substrate site for cellular attachment, Okita is similarly deficient. Where a reference teaches away from the combination asserted, the references are not properly combinable. *In re Fine*, 5 USPQ 2d 1596 (Fed. Cir. 1988); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986).

It is therefore respectfully submitted that claims 1 and 13 are patentably distinct over the cited combination and reversal of the Examiner's Final Rejection thereof is warranted.

2. **The rejection of claims 1-10, 13-16 and 18 as being obvious over Hoffman in view of Okita**

Hoffman discloses textile vascular graft in which pores of the graft include collagen. It is acknowledged by the Examiner that the Hoffman disclosure is limited to textile grafts and there is no disclosure in Hoffman of the use of either a PTFE substrate or an expanded PTFE substrate. The Examiner combines with Hoffman the teaching of Okita for its basic disclosure of ePTFE grafts.

At the outset, it is noted that Hoffman provides a textile graft where substantial spaces are provided between the textile material. In textile grafts, in order to prevent blood leakage, it is commonly known to apply collagen to make the graft blood-tight. As Hoffman is directed solely to textile grafts, it does not address the problems inherent with micropores exhibited by ePTFE grafts. Use of ePTFE grafts does not present the same concerns with respect to blood tightness. Rather, the pores of the ePTFE graft are beneficial in that microporous structure facilitates tissue ingrowth without exhibiting leakage common in textile grafts. The present invention enhances cellular attachment to the graft by placing a biocompatible composition within the micropores of the ePTFE graft. Hoffman fails to address at all such a structure and function.

As noted above, Okita, which is combined with Hoffman, is completely silent on the use of a composition within its pores to promote cellular attachment. In fact, as noted above, Okita discloses the opposite proposition, that of preventing absorption of plasma protein into the pores. Therefore, even if combined with Hoffman, the combination still fails to disclose, teach or suggest an ePTFE graft having a microporous structure with a biodegradable composition within the pores to enhance cellular attachment.

It is therefore respectfully submitted that claims 1 and 13 define patentably over the cited combination, and reversal of the Final Rejection thereof is warranted.

3. The rejection of claims 1-8, 11, 13-16 and 18 is obvious over Alonso in view of Okita

The Alonso reference is cited as a further example of vascular grafts formed of various textile materials. In that regard, the Alonso disclosure is similar to the Hoffman reference discussed above.

Collagen is impregnated in the Alonso vascular graft for the same purposes discussed in Hoffman, primarily to render the graft blood-tight. The is no disclosure in Alonso of an ePTFE graft. As noted, Okita is silent with respect to use of any composition to promote cellular attachment. Therefore, for the reasons set forth above with respect to the combination of Hoffman and Okita, the combination of Alonso and Okita also fails to disclose, teach or suggest the structure claimed in claims 1 and 13 of the present invention.

Therefore, reversal of the Examiner's Final Rejection of claims 1 and 13 over Alonso in view of Okita is warranted.

4. The rejection of claim 13 under 35 U.S.C. §103 as being obvious over Jernberg

The teachings of the Jernberg reference are discussed above. As noted, Jernberg does not disclose that the pores of the ePTFE structure are filled with a biodegradable composition which serves as a site for cellular attachment. The chemotherapeutic microspheres of Jernberg, even if, as suggested by the Examiner, are provided within the matrix of the ePTFE

structure, do not remain with the structure so as to serve as a site for cellular attachment as specifically claimed in claim 13 herein. While the microspheres of Jernberg may be introduced into the micropores of the graft, they do not substantially fill the pores and do not remain within the graft sufficiently long to establish a site for cellular attachment. The biodegradable materials utilized in Jernberg are designed for release into the bloodstream rather than remaining with the graft to promote cellular attachment. As such, Jernberg fails to disclose, teach or suggest the structure set forth in claim 13.

Additionally, the Examiner posits that the microparticles of Jernberg "would not prevent cellular attachment [and therefore] would function to be a site for cellular attachment" (Office Action mailed July 26, 2001 at page 10). It is respectfully submitted that the Examiner is applying the Jernberg reference in a manner beyond that which is disclosed, taught or suggested by the reference. Jernberg is completely silent on the issue of cellular attachment. There is no disclosure within Jernberg as to whether the microparticles would enhance cellular attachment. In fact, it appears just the opposite is true, since the microparticles are designed for release of a chemotherapeutic agent, it is unlikely that microparticles would permit cellular attachment thereto.

Accordingly, it is respectfully submitted that claim 13 is patentably distinct over Jernberg and therefore reversal of the Examiner's Final Rejection is warranted.

C. OTHER REJECTIONS

1. The rejection of claims 13-18 under 35 U.S.C. §251

The Examiner contends that claims 13-18 constitute an improper recapture of broadened claim subject matter surrendered in the application for patent upon which the present reissue is based. The Examiner contends that the claim language such as "fill with fluid which solidifies it is cross-linked to form" and "said material being insoluble at a pH at about 7.4" was added in order to overcome a prior rejection. The Examiner concludes that inasmuch as claim 13 does not include the quoted language, it constitutes an improper attempt to recapture subject matter in violation of 35 U.S.C. §251.

Contrary to the Examiner's conclusion, claim 13 does not constitute improper recapture. The recapture doctrine seeks to prevent an applicant from recapturing subject matter via reissue which was intentionally abandoned during original prosecution. The doctrine of recapture prevents a reissue applicant using reissue as a means by which to bypass the patent appeals process. A reissue claim, however, does not fall within the scope of the recapture doctrine if the reissue claim is materially different from the surrendered claim. The courts have established a test to determine if a reissue claim is materially different from the surrendered original claim. One such test sets forth that, where a reissue claim is more restrictive in at least one significant aspect than the canceled claim, it will not be subject to the recapture doctrine. *In re Richman*, 161 USPQ 359 (CCPA 1969); *Ball v. United States*, 221 USPQ 289 (Fed. Cir. 1984). Thus, it is well-established case law that by restricting a

reissue claim in at least one significant aspect with respect to the abandoned claim, the recapture doctrine may be avoided. *Id.*

In the instant case, reissue claim 13 differs from original claim 1 in at least one significant aspect. Claim 13 recites that the biodegradable composition substantially fills the pores of the ePTFE structure. Surrendered claim 1 in the original parent case did not include the limitation of the biodegradable composition substantially filling the pores. In that regard, reissue claim 13 is narrower than surrendered claim 1. Furthermore, reissue claim 13 includes limitations directed to biodegradable composition forming a precipitate at selective conditions of both temperature and pH. In surrendered claim 1, there was no limitation directed to temperature considerations. Therefore, reissue claim 13 is narrower with respect to the temperature limitation. Additionally, reissue claim 13 specifically recites that the composition in the pores establishes a site for cellular attachment. This limitation is absent in surrendered claim 1.

It is clear that with respect to at least three aspects, reissue claim 13 differs from and is narrower than surrendered claim 1. It is therefore submitted that under applicable case law, the application of the recapture doctrine is not appropriate with respect to claim 13.

The Examiner posits that limitations above noted with respect to claim 13 "do not sufficiently distinguish it from the surrendered claim" (Office Action mailed July 26, 2001 at page 8). The Examiner further summarizes the patent prosecution which occurred during the original patent. Appellants do not dispute the Examiner's interpretation of the previous

prosecution. Notwithstanding the arguments made during patent prosecution, application of the recapture doctrine should be based on the "materially different" standard set forth in case law. Thus, even where an element argued during prosecution is broadened during reissue, if the claim includes a narrower limitation in at least one significant aspect and is thereby materially different, the claim does not constitute impermissible recapture.

It is therefore submitted that, by the inclusion of limitations relating to the pores of the graft being substantially filled, temperature parameters and establishing a site for cellular attachment, claim 13 includes narrower limitations and is therefore materially different from surrendered claim 1.

Having established both factually and legally that claim 13 is materially different from surrendered claim 1 in the original patent, reissue claim 13 is submitted as not being violative of the recapture doctrine and therefore is allowable.

Reversal of the Examiner's rejection is respectfully requested.

2. <u>Offer to surrender original patent</u>

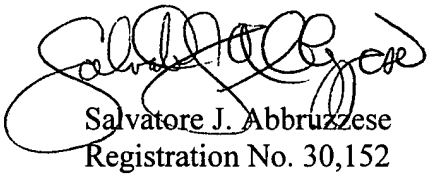
The Examiner has indicated that the original patent, or an affidavit or declaration as to the loss or inaccessibility of the original patent, must be received before the reissue application can be allowed. Upon receipt of indication of allowable subject matter, the

original patent and/or an affidavit or declaration as to its loss or inaccessibility will be supplied.

IX. CONCLUSION

For the factual and legal reasons set forth above, it is respectfully submitted that the application, including claims 1-18, is in condition for allowance. Reversal of the Examiner's final rejection is believed to be warranted.

Respectfully submitted,



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CLAIMS CURRENTLY ON APPEAL

1. An implantable member for use in repair or replacement with a body comprising an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils with pores present between said nodes and said fibrils, said pores filled with a fluid which solidifies and is crosslinked to form a solid precipitate of a insoluble biocompatible, biodegradable material of natural origin said material being insoluble at a pH of about 7.4.

2. An implantable member of claim 1 wherein said substrate comprises an implantable tubular prosthesis.

3. An implantable member of claim 1 wherein said substrate comprises an implantable surgical patch.

4. An implantable member of claim 1 wherein said substrate comprises an implantable mesh.

5. An implantable member of claim 1 wherein the insoluble biocompatible, biodegradable material substantially fills said pores to render the substrate blood-tight.

6. An implantable member of claim 1 wherein the biocompatible, biodegradable material includes extracellular matrix proteins.

7. An implantable member of claim 6 wherein said extracellular matrix protein is selected from the group consisting of collagen I–V, gelatin, vitronectin, fibronectin, laminin, reconstituted basement membrane matrices and derivatives and mixtures thereof.

8. The prosthesis of claim 1 wherein the biocompatible, biodegradable material is cross-linked.

9. The prosthesis of claim 1 wherein the biocompatible, biodegradable material includes a pharmacological agent.

10. The prosthesis of claim 9 wherein said pharmacologically active agent is selected from the group consisting of antimicrobials, antivirals, antibiotics, growth factors, blood clotting modulators, antivirals and mixtures thereof.

11. The prosthesis of claim 1 wherein the polytetrafluoroethylene has been modified to enhance its hydrophilic character.

12. The prosthesis of claim 11 wherein the polytetrafluoroethylene has been subjected to glow discharge plasma deposition.

13. An implantable prosthesis comprising a body of expanded polytetrafluoroethylene having a structure of spaced apart nodes interconnected by fibrils with pores present between said nodes and said fibrils; and a biodegradable composition of natural origin contained within said pores, said biodegradable composition forming a precipitate that substantially fills said pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment.

14. An implantable prosthesis of claim 13 wherein said biodegradable composition includes extracellular matrix proteins or gelatins.

15. An implantable prosthesis of claim 14 wherein said composition is selected from the group consisting of collagen I, collagen II, collagen III, collagen IV, collagen V, gelatin, vitronectin, fibronectin, laminin, reconstituted basement membrane matrices and derivatives and mixtures thereof.

16. An implantable prosthesis of claim 14 wherein said extracellular matrix protein comprises collagen.

17. An implantable prosthesis of claim 14 wherein said composition includes a buffered phosphate.

18. An implantable prosthesis of claim 17 wherein said buffered phosphate is maintained at a pH of about 7.4.